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## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

8932-726-999

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on \_\_\_\_\_

Signature \_\_\_\_\_

Typed or printed name \_\_\_\_\_

Application Number

10/783,233

Filed

2/19/04

First Named Inventor

Ross J. Hamel

Art Unit

3733

Examiner

David C. Comstock

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐

applicant/inventor.

☐

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)

☒

attorney or agent of record.

Registration number 40,210

☐

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

Signature

Garry J. Tuma

Typed or printed name

212-326-7845

Telephone number

April 12, 2007

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

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\*Total of 1 forms are submitted.

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Express Mail No. EV473971002US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION

Applicant:	Ross J. Hamel	Confirmation No.:	7395
Application No.:	10/783,233	Art Unit:	3733
Filed:	February 19, 2004	Examiner:	David C. Comstock
For:	CRANIOFACIAL FRACTURE REDUCTION ASSEMBLY	Attorney Docket:	8932-726-999

New York, New York 10017  
April 12, 2007

Mail Stop AF  
Hon. Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REMARKS FOR PRE-APPEAL BRIEF CONFERENCE**

Sir:

Applicant requests review of all rejections in the February 12, 2007 final Office Action ("FOA"), because prima facie anticipation and obviousness have not been established.

**Status of Claims**

All independent claims (1, 41, and 72) stand rejected under 35 U.S.C. §102(b) as being anticipated by Standerwick et al. U.S. Patent No. 3,072,118 (hereinafter "Standerwick").

Dependent claim 6 stands rejected under 35 U.S.C. §103(a) as being obvious from Standerwick. The remaining dependent claims stand either withdrawn or rejected based on Standerwick alone or in combination with another reference.

**The Standerwick Reference**

Standerwick purportedly discloses a fracture appliance that "may be fixed with greater rigidity to the skull and which will be comfortable, light, readily applied and not subject

to the disadvantages of plaster head caps and the like” (column 1, lines 46-49). More particularly, an object of Standerwick is “to provide a skull-attached frame adapted ... to simplify and to make possible the more rapid application of the frame, of the attachments and of the connections between the attachments and other parts” (*id.* at lines 53-61).

**Standerwick Does Not Anticipate Independent Claims 1 and 41**

Independent claim 1 requires a fragment manipulator having a bone engaging end configured to attach to a bone fragment such that the bone fragment can be pulled toward a reduction platform to reduce the fracture. Independent claim 41 similarly requires the bone engaging end to have a thread attachable to a bone fragment such that the bone fragment can be pulled toward a reduction platform.

The Examiner said that Standerwick discloses “a fragment manipulator ... having a bone engaging end 33” (FOA, page 2). The Examiner also said “a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.” The Examiner then asserted that “Standerwick et al. discloses the claimed structure and is at least capable of performing the intended use as set forth in Applicant’s claims” (*id.* at page 5).

Applicant argued that (1) a structural difference does indeed exist between the claimed invention and Standerwick’s “fragment manipulator,” which the Examiner says may be mounting pin 8, and (2) this structural difference is why Standerwick’s mounting pin 8 is not capable of performing bone fracture reduction (*see* applicant’s November 16, 2006 Reply, pages 16-17).

Structurally, Standerwick only discloses that its mounting/fixing pins have a “bone-piercing drill point 33” (column 2, line 51) and that its stabilizing pin 10 “comprises merely a sharp conical point 46” (column 3, lines 8-9). Standerwick’s FIG. 1 shows that drill point 33 and conical point 46 are structurally only pointed.

Applicant explained that not all bone-piercing drill points are capable of reducing bone fractures. To reduce a bone fracture, the tips of Standerwick’s pins must have some structure, such as, for example, threads, ribs, or other aggressive means to provide sufficient axial pull resistance in order to pull a bone fragment upward towards Standerwick’s head frame. As shown and disclosed, the tips of Standerwick’s pins do not.

In contrast, applicant’s specification describes a fragment manipulator having a bone engaging end configured with two types of threads: one with an increasing diameter to penetrate the fractured bone piece and the other with a uniform diameter to securely attach to the fractured bone fragment such that the bone fragment can be pulled upward (*see* specification, page 7, line 32, to page 8, line 1, and FIG. 3b).

Plainly, there is a structural difference between the bone engaging end of applicant’s fragment manipulator and the pins disclosed by Standerwick that renders Standerwick’s pins incapable of reducing a bone fracture.

The Examiner replied by merely repeating his previous assertion without addressing applicant’s arguments (FOA, page 5). Moreover, the Examiner did not cite any evidence to show that Standerwick’s mounting or stabilizing pins 8-12 have the structure necessary to perform fracture reduction.

**Standerwick Does Not Anticipate Independent Method Claim 72**

This claim requires locating a bone to be reduced and rotating a nut to reduce the located bone.

In finally rejecting claim 72, the Examiner said that Standerwick's manipulator (e.g., mounting pin 8), when "engaged in bone and a top nut is turned, ... is urged upward together with the bone attached thereto" (FOA, page 6; emphasis added).

This is pure speculation.

Applicant has found no such disclosure in Standerwick and argued that Standerwick' mounting pin 8 could not perform this method because the structure necessary to do so was not disclosed.

The Examiner further erroneously stated that "[f]inally, and with respect to the method claims, it is noted that 'reduction' is only mentioned in the preamble and not in any positive steps of the method" (FOA, page 6). Not true. Applicant amended claim 72 in his April 19, 2006 Reply and again pointed out that amendment in his November 16, 2006 Reply (see page 19).

**Standerwick Does Not Render Obvious Dependent Claim 6**

Dependent claim 6 requires the bone engaging end to have a first portion with increasing diameter threads and a second portion with uniform diameter threads.

The Examiner acknowledged that Standerwick does not disclose a drill tip having expanding and constant diameter threads, but said that "such threaded tips and drill point tips are equivalent self-drilling structures known in the art" and that it would have been obvious to modify Standerwick because "this merely involves substitution of functionally equivalent structures" (FOA, page 3).

Applicant explained that not all self-drilling tips and not all bone-piercing drill points are capable of reducing bone fractures and argued that Standerwick's drill point tips are not functionally equivalent to applicant's bone engaging end. Standerwick's drill points and sharp conical points perform the function of penetrating a skull in order to mount and stabilize a head frame, while applicant's bone engaging end performs the function of resisting axial pull away from the skull in order to reduce a bone fracture (November 16, 2006 Reply, page 18).

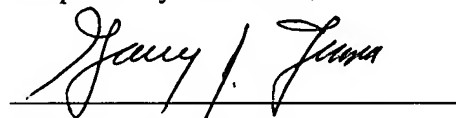
Applicant accordingly argued that Standerwick provides no motivation for modifying its mounting pins to include applicant's multi-diameter threads.

The Examiner did not cite any evidence to support his assertion that a person of ordinary skill in the art would be motivated to modify the pin tips of Standerwick such that they could perform fracture reduction or that such a pin tip modification would result in applicant's multi-diameter threads as defined in claim 6.

### **Conclusion**

In sum, Standerwick does not disclose mounting, fixing, or stabilizing pins that are capable of performing bone reduction. Moreover, Standerwick does not disclose that those pins have any structure capable of resisting axial pull. Thus, Standerwick does not anticipate or render obvious applicant's invention as claimed.

Respectfully submitted,



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